Appl. No. 09/938,112 Reply to Office Action of December 21, 2004

#### Remarks

# Introduction

The above-identified application has been carefully reviewed in light of the Office Action mailed December 21, 2004, which included a final rejection of the pending claims. This Amendment is being submitted within TWO MONTHS of the mailing date of the Final Office Action. Applicant submits that the amendments and remarks included herein show the present claims to be allowable and do not raise new issues. Therefore, applicant respectfully requests that this amendment be entered.

Claims 21, 22, 36, 37, 67-75, 77, and 78 were pending. By way of this response, claims 21, and 69 have been amended. Claim 21 has been amended by deleting the phrase "or recombinantly fusing", and claim 69 has been amended to be consistent with claim 70. Accordingly, claims 21, 22, 36, 37, 67-75, 77, and 78 remain pending.

# Rejections Under 35 U.S.C. §§ 101 and 112, first paragraph

Claims 21 and 22 have been rejected under 35 U.S.C. § 101, as allegedly being inoperative and lacking utility. Claims 21 and 22 have also been rejected under 35 U.S.C. § 112, first paragraph for allegedly not being described in the specification of the above-identified application. For the record, applicant notes that the Office Action indicates that claims 20 and 21 have been rejected under 35 U.S.C. § 112, first paragraph. Claim 20 was cancelled in the amendment filed on August 23, 2001. Applicant assumes that the Examiner was referring to claims 21 and 22, as indicated above.

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Applicant does not concede with the rejections or the remarks made in the Office Action. However, to advance the prosecution of the above-identified application, claim 21 has been amended by deleting the phrase "or recombinantly fusing", which was objected to by the Examiner. The amendment to claim 21 similarly applies to dependent claim 22.

In view of the above, applicant submits that the present claims, and claims 21 and 22 in particular, satisfy the requirements of 35 U.S.C. §§ 101 and 112, first paragraph, and respectfully requests that the rejections of the present claims based on these statutory provisions be withdrawn.

# Rejection Under 35 U.S.C. § 112, second paragraph

Claims 69, 70, 71, and 73-75 have been rejected under 35 U.S.C. § 112, second paragraph. The Office Action states that the term "substantially identical" renders the claims indefinite.

Applicant traverses the rejection.

Applicant submits that the term "substantially identical" does not render the present claims indefinite. As used in the specification of the above-identified application, the term "substantially" refers to agents or components that have the same function or functions as that of the agent or component from which they are derived or compared (e.g., see page 24, lines 19-22).

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Applicant submits that the use of the word "substantial" or "substantially" does not render claims indefinite. "Claims need only 'reasonably apprise those skilled in the art' as to their scope to satisfy the definiteness requirement (Energy Absorption Sys., Inc. v. Roadway Safety Servs., Inc., Civ. App. 96-1264 (Fed. Cir. July 3, 1997 (unpublished) (citing Hybridtech v. Monoclonal Antibodies, Inc., 802 F.2d 1367, 1385, 231 USPQ 81, 94 (Fed. Cir. 1986), cert. denied, 480 U.S. 947 (1987)).

In the present case, the use of the term substantially identical refers to an amino acid sequence of an expressed clostridial neurotoxin that is similar to another clostridial expressed clostridial neurotoxin neurotoxin such that the functions similarly to the clostridial neurotoxin to which the expressed clostridial neurotoxin is being compared. understood by persons of ordinary skill in the art, proteins can have conservative amino acid substitutions or modifications and still function similarly to a native or naturally occurring Thus, applicant submits that the term "substantially protein. identical" does not render the present claims indefinite.

In view of the above, applicant submits that the claims satisfy the requirements of 35 U.S.C. § 112, second paragraph, and respectfully requests that the rejection of the present claims based on this statutory provision be withdrawn.

### Allowed Claims

Claims 36, 37, 67, 68, 72, 77, and 78 are indicated as being allowable. In view of the amendments to the claims set forth herein, applicant submits that all of the present claims,

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that is claims 21, 22, 36, 37, 67-75, 77, and 78, are in condition for allowance.

## Conclusion

In conclusion, applicant has shown that the present claims satisfy the requirements of 35 U.S.C. §§ 101 and 112. Therefore, applicant submits that the present claims, that is claims 21, 22, 36, 37, 67-75, 77, and 78, are allowable. Therefore, applicant respectfully requests the Examiner to pass the above-identified application to issuance at an early date. Should any matters remain unresolved, the Examiner is requested to call (collect) applicant's attorney at the telephone number given below.

Date: 2/21/05

Respectfully submitted.

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